



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

Handwritten signature

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,953	09/27/2000	Claude Meares	2307O-099120US	8313
43850	7590	06/17/2005	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP (SF) 2 PALO ALTO SQUARE PALO ALTO, CA 94306			HELMS, LARRY RONALD	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 06/17/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/671,953	MEARES ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on the amendment filed 5/31/05.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 10, 11, 14-25, 42, 45 and 46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3, 10-11, 14-24, 42, 45-46 is/are allowed.
- 6) ☐ Claim(s) 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

KLS

DETAILED ACTION

1. Claims 1-3, 10-11, 14-25, 42, 45-46 are pending.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejection Withdrawn

3. The rejection of claim 44 under 35 U.S.C. § 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from the written description is withdrawn in view of the amendments to the claims.

The Following is a NEW GROUND of Rejection

4. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Reardan et al (Nature 316:265-267, 1985, IDS #7) and further in view of Orlandi et al (Proc. Natl. Acad. Sci. USA 86:3833-3837, 1989) and Pastan et al (U.S. Patent 5,747,654, issued 5/5/98, IDS #8).

Claim 25 recites a mutant antibody comprising a cysteine residues not in the wild-type and the antibody binds a chelate and the cysteine is in a position proximate to a CDR and the cysteine is the mutation.

Art Unit: 1642

Reardan et al teach antibodies to metal chelates and specifically the CHA255 antibody and hybridoma. Reardan does not teach an antibody comprising a cysteine mutation. This deficiency is made up for in the teachings of Orlandi and Pastan.

Orlandi et al teach a method of cloning variable domains from hybridomas.

Pastan et al teach a method of stabilizing an antibody by adding a cysteine in the region proximate to a CDR (see column 2, lines 5-35 and Figure 1).

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced a mutant antibody that binds a chelate and comprises a cysteine residue as the mutation in view of Reardan, Orlandi, and Pastan.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a mutant antibody that binds a chelate and comprises a cysteine residue as the mutation in view of Reardan, Orlandi, and Pastan because Reardan et al teaches a hybridoma that produces an antibody that binds a metal chelate and the antibody can be used for diagnostics and treatment of humans and it would have been obvious to obtain the DNA of the hybridoma in view of Orlandi. In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced a mutant antibody that binds a chelate and comprises a cysteine residue as the mutation in view of Reardan, Orlandi, and Pastan because Pastan teaches adding a cysteine to the antibody for stability and in view of Reardan who teaches the antibody for treatment, it would have been obvious to stabilize the antibody of Reardan as a scfv for treatment. Because the claim only

Art Unit: 1642

requires a cysteine mutation and not that the cysteine be available for binding to a reactive site. The art reads on the claim.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

5. Claims 1-3, 10-11, 14-25, 42, 45-46 are in condition for allowance.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.
7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 571-273-8300.

Application/Control Number: 09/671,953


Page 5

Art Unit: 1642

Respectfully,

Larry R. Helms Ph.D.

571-272-0832



LARRY R. HELMS, PH.D.
PRIMARY EXAMINER